FEB 9 2006

Clinical Data, Inc.

USA: One Gateway Center, Suite 415 Newton, MA 02158
1-617-527-9933, Ext. 22 Fax: 1-617-527-8230

510(k) Summary

Nanopia Wide Range CRP

The assigned 510(k) Number is: K052591

A. Analyte:
C-Reactive Protein (CRP)

B. Type of Test:
Turbidimetric immunoassay

C. Applicant:
One Gateway Center, Suite 415
Newton, MA 02158
Phone: 617-527-9933, Ext. 41
Fax: 617-527-8230

D. Proprietary and Established Names:
Nanopia Wide Range CRP Reagent
Nanopia Wide Range CRP Calibrator

E. Regulatory Information:

1. Regulation section:
   21 CFR § 866.5270, C-reactive protein immunological test system
   21 CFR § 862.1150, Calibrator
2. Classification:
   Class II
3. Product Code:
   DCK, C-reactive protein, antigen, antiserum, and control
   JIS, Calibrator, primary
4. Panel:
   Immunology (82)

F. Intended Use:

1. Intended use(s):

   The Nanopia Wide Range CRP Reagent is intended for the quantitative measurement of C-Reactive Protein (CRP) concentration in serum or plasma.

   Measurement of CRP is useful for determining the existence of inflammatory lesions and to monitor treatment.

   The Nanopia Wide Range CRP Calibrator is intended for the calibration of the Nanopia Wide Range CRP assay.

2. Indication(s) for use:
   See Intended Use section.

3. Special condition for use statement(s):
   For *in vitro* diagnostic use.

   Increases in CRP values are non-specific and should not be interpreted without a complete clinical history.

4. Special instrument Requirements:
   Clinical chemistry analyzers (testing performed on Roche Hitachi 917 analyzer)

G. Device Description:

The Nanopia Wide Range CRP assay consists of two liquid reagents. Reagent 1 is a buffering solution and Reagent 2 contains latex beads coated with mouse monoclonal anti-human CRP antibodies. The assay is for use on general clinical chemistry analyzers.

H. Substantial Equivalence Information:

1. Predicate device name(s):
   N-Geneous Wide Range CRP Reagent.

2. Predicate K number(s):
   K040241

3. Comparison with predicate:

Item	Device	Predicate
Intended Use	Quantitative measurement of CRP in serum or plasma	Quantitative measurement of CRP in serum or plasma
Sample Matrix	Serum or plasma	Serum or plasma
Antibody	Mouse monoclonal anti-human CRP	Mouse monoclonal anti-human CRP
Assay Range	0.1 to 400 mg/L	0.04 to 320 mg/L
Antibody substrate	Latex	Latex
Number of calibrators	5	5

The N-Geneous Wide Range CRP Reagent and the Nanopia Wide Range CRP are essentially the same product both produced by Daiichi Pure Chemicals Co., Ltd. for distribution by the respective companies.

I. Standard/Guidance Document Referenced (if applicable):

NCCLS Guideline EP9-A - Method Comparison and Bias Estimation Using Patient Samples
NCCLS Guideline EP5-A - Evaluation of Precision Performance of Clinical Chemistry Devices
NCCLS Guideline EP6-A - Evaluation of the Linearity of Quantitative Analytical Methods
NCCLS Guideline EP7-A - Interference Testing in Clinical Chemistry

J. Test Principle:

Sample is mixed with the buffer solution and the anti-CRP antibody–coated beads. CRP in the sample binds the antibody-coated beads and agglutinates. The light scattering caused by an increase in particle size is measured. The amount of light scattering is proportional to the concentration of CRP in the sample.

K. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Device imprecision was evaluated according to NCCLS EP5-A. Spiked serum samples were run in triplicate daily for 20 days (units = mg/L).

Control	Mean	Within Run		Total	
		SD	% CV	SD	% CV
1	0.886	0.16	1.83	0.022	2.46
2	6.71	0.05	0.76	0.089	1.31
3	38.88	0.24	0.61	0.430	1.11

b. Linearity/assay reportable range:

The useable range of this device is 0.10 – 400 mg/L (the Limit of Quantification to the upper end of the linear range).

Linearity was assessed using a sample with CRP values of 400 mg/L. Using a serum pool free of CRP dilutions were prepared to create samples with theoretical concentrations from 40 to 400 mg/L in increments of 40 mg/L. A sample from a serum pool free from CRP was included for a zero concentration. These samples were run in duplicate and the actual mean values were compared to the theoretical values. The % recovery from 0 to 400 mg/L ranged from 97.5 to 102.7%. Results are summarized below (units = mg/L).

(mg/L)

Theoretical CRP value	measurement value			% Recovery
	1	2	mean	
0	0.00	0.00	0.00	----
40	39.33	40.20	39.77	99.4
80	79.01	78.42	78.72	98.4
120	119.26	116.14	117.70	98.1
160	155.44	156.48	155.96	97.5
200	196.46	194.97	195.72	97.9
240	236.89	236.10	236.50	98.5
280	280.76	278.09	279.43	99.8
320	322.15	323.21	322.68	100.8
360	374.30	365.09	369.70	102.7
400	401.12	406.17	403.65	100.9

The acceptable criteria was 100% ± 5%

The results above indicate that the assay is linear across the measuring range of the assay.

c. Traceability (controls, calibrators, or method):

The device is calibrated by a set of 5 calibrators (sold separately) with targeted CRP concentrations of 3, 6, 30, 180 and 360 mg/L. The calibrator is traceable to CRM470. A master calibrator is prepared and value assigned by multiple measurements of multiple lots using the device. The calibrators are traceable to this master calibrator and are value assigned using the device. Stability testing is described.

d. Detection limit:

Analytical sensitivity, defined as the lowest concentration at which the assay performs with + 2 SD as assessed by diluting a serum sample with a concentration of 0.5 mg/L to 0.0 mg/L and measuring the mAbs in replicates of 10. By this method, the functional sensitivity of this assay is said to be 0.10 mg/L (derived by extrapolation of plot of theoretical concentration vs. recovered concentration.

e. Analytical specificity:

Interference of endogenous substances was evaluated by testing for the effect of hemoglobin (up to 500 mg/dL), ascorbic acid (up to 100 mg/dL), free bilirubin (up to 50 mg/dL), conjugated bilirubin (up to 50 mg/dl, lipid emulsion (up to 5000 turbidity), Rheumatoid factor (up to 500 IU/mL), and ascorbic acid (up to 100 mg/dL) on serum samples containing a nominal concentration of 3.7 mg/L. No interference was noted on any of the above. Interference was defined as a result +/- 5 % of the control. This information is in the package insert.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Serum samples (n=98) ranging from 0.0 to 293 mg/L were measured using the Nanopia method and comparing those measurement to those made with the predicate method. Results are summarized below.

Serum Samples: Nanopia = 1.015(Predicate) - 0.0349; $R^2 = 0.9992$

b. Matrix comparison:

Paired samples of serum and EDTA plasma were collected concurrently from 50 individuals and measured using the Nanopia method. Results are summarized below:

Plasma = 0.994(Serum) + 0.03; r = 0.999

Additional serum pools were spiked with 110 mM of sodium citrate, 100 mM sodium oxalate, 25 mM EDTA, and 100 U/mL of sodium heparin and assayed. There were no significant differences observed between sample types.

3. Clinical studies:
   a. *Clinical sensitivity:*
      Not applicable
   b. *Clinical specificity:*
      Not applicable
   c. *Other clinical supportive data (when a and b are not applicable):*
      Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Less than 3.0 mg/L.

L. Conclusion:

Clinical Data concludes that the Nanopia Wide Range CRP assay has a similar intended use, a similar technological principle, and clinically acceptable performance comparable to similar devices currently in commercial distribution and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 9 2006

Israel M. Stein, MD
President
Clinical Data, Inc.
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Suite 411
Newton, MA 02146

Re: k052591
Trade/Device Name: Nanopia Wide Range CRP Reagent
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK, JIS
Dated: January 12, 2006
Received: January 13, 2006

Dear Dr. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052591

Device Name: Nanopia Wide Range CRP Reagent

Indications For Use: The Nanopia Wide Range CRP Reagent is intended for the quantitative measurement of C-Reactive Protein (CRP) in serum or plasma. The assay is intended for use in the evaluation of infection, tissue injury, and inflammatory disorders in combination with a complete clinical evaluation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chaper

Office of In Vitro Diagnostic Device Evaluation and Safety

K052591